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Certifier	<i>[Signature]</i>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-0505]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Substances Prohibited From Use in Animal Food or Feed; Animal Protein Prohibited in Ruminant Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Title: Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed—21 CFR Part 589—(OMB Control No. 0910-0339)—Extension

Description: This rule (§ 589.2000 (21 CFR 589.2000)) provides that protein derived from mammalian tissue (with some exceptions) for use in ruminant feed is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348). Proteins derived from animal tissues contained in such feed ingredients in distribution cannot be readily identified (i.e., species), by recipients engaged in the manufacture, processing and distribution, and use of animal feeds and feed ingredients.

Thus, under the agency's authority in section 701(a) of the act (21 U.S.C. 371(a)), to issue regulations for the efficient enforcement of the act, this rule places three general requirements on persons that manufacture, blend, process, distribute, or use products that contain or may contain protein derived from mammalian tissues and feeds made from such products. The first requirement is for cautionary labeling of these products with direct language developed by FDA. This labeling requirement is exempt from the scope of the PRA because it is a "public disclosure of information originally supplied by the Federal Government for the purpose of disclosure to the public" (5 CFR 1329.3(c)(2)).

The second requirement is for establishments to maintain and make available to FDA, records that are sufficient to track any material that contains protein derived from mammalian tissues (as defined in § 589.2000(a)(1)), throughout the material's receipt, processing, and distribution. Based on available information, FDA believes that maintenance of these records is a usual and customary part of normal business practices for these firms. Therefore, this recordkeeping requirement creates no additional paperwork burden.

The third requirement is that individuals or firms that manufacture, blend, process, or distribute both mammalian and nonmammalian materials must maintain written procedures to prevent commingling and cross-contamination. An estimate of the burden resulting from this recordkeeping

requirement is provided in table 1 of this document. The estimate is based on the time required to develop written procedures.

Respondents to this collection of information are individuals or firms that manufacture, blend, process distribute, or use feed or feed ingredients that contain or may contain protein that may be derived from mammalian tissue.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹


21 CFR Section	No. of Recordkeepers	Annual Frequency per Response	Total Annual Records	Hours per Record	Total Hours
589.2000(e)(1)(iv)	1,030	1	1,030	14	14,420

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated number of respondents, persons that separate mammalian and nonmammalian materials, is derived from inspections of firms handling animal protein intended for use in

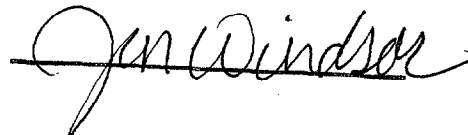
animal feed. The estimate of the time required for this recordkeeping requirement is based on agency records and communication with industry.

Dated: June 14, 2000



William K. Hubbard
Senior Associate Commissioner for
Policy, Planning, and Legislation

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COPY OF THE ORIGINAL



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